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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No: 2004N-0264

Dear Sir or Madame:

On behalf of McDonald's Corporation, which operates more than 13,000 restaurants in the United States, we appreciate the opportunity to submit comments to this very important Advance Notice of Proposed Rulemaking (ANPRM). 69 Fed. Reg. 42288 (July 14, 2004). After the identification of bovine spongiform encephalopathy (BSE) in the second indigenous North American cow, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect public health. Given what is known about the epidemiology and characteristically long incubation period of BSE, additional regulations from the Food and Drug Administration (FDA) are overdue.

Scientific and epidemiological findings provide more than ample support for further actions regarding the feed ban in the United States. These actions are imperative to prevent further recycling of the BSE agent within the North American cattle herd.

We feel that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which

2004N-0264

C26

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allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued.<sup>1</sup>

SRMs, as defined by the USDA, are tissues which, in a BSE infected animal, are known to either harbor BSE infectivity or to be closely associated with infectivity. [NOTE: Does McDonald's want to use the same definition of SRMs as FDA used in its interim final rule for human food? If so, comments probably should say so. Also, it is not clear what is meant by tissues "closely associated with infectivity." FDA's description in the preamble to the ANPRM (footnote 4) states that SRMs are "ruminant tissues that have demonstrated infectivity at some point during the BSE incubation period."] If SRMs are not removed, they may introduce BSE infectivity and continue to provide a source of animal feed contamination. Rendering will reduce infectivity but it will not totally eliminate it. This is significant as research in the United Kingdom has shown that a calf may be infected with BSE by the ingestion of as little as .001 gram of untreated brain.

With the current feed ban, it is still possible for cattle to be exposed to BSE through:

1. Feeding of materials currently subject to legal exemptions from the ban (*e.g.*, poultry litter, plate waste)
2. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms; and
3. Cross contamination of ruminant and non-ruminant feed

A number of authoritative bodies also agree with the position that removing SRMs and deadstock from all animal feed would reduce the BSE risk within the US.

#### World Health Organization

The World Health Organization (WHO) has issued the following recommendations for countries with BSE or those where a known exposure exists:

"No part or product of any animal which has shown signs of a TSE should enter any food chain (human or animal). In particular:

- All countries must ensure the killing and safe disposal of all parts or products of such animals so that TSE infectivity cannot enter any food chain.

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<sup>1</sup> The exemption for milk and milk products from the existing feed ban should be retained, because there is no scientific evidence that BSE can be transmitted through milk.

**- Countries should not permit tissues that are likely to contain the BSE agent to enter any food chain (human or animal)."**

Report of a WHO Consultation on Public Health Issues related to Human and Animal Transmissible Spongiform Encephalopathies WHO/EMC/DIS 96.147, Geneva, 2-3 April 1996 (emphasis added).

#### Harvard/Tuskegee BSE Risk Assessment

Per the Executive Summary of its 2001 release, the Harvard/Tuskegee Study states, "Specific pathways or practices that would contribute the most to the spread of BSE if it were introduced into the U.S. relate to compliance with the FDA feed ban and include misfeeding on the farm and the mislabeling of feed and feed products prohibited for consumption by cattle. The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if this disease were introduced into the U.S."

The report continues:

- "Our evaluation of potential risk mitigation actions highlights potential measures to further reduce the already low likelihood that BSE could spread to cattle or contaminate human food if it were to arise. Prohibiting the rendering of animals that die on the farm, possibly of BSE, removes a great deal of potential contamination in the animal feed chain and reduces average predicted cases of BSE following introduction of ten infected cattle by 77%. Implementation of a UK-style ban on specified risk material (e.g., spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%."
- "The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced." The base case scenario showed that the mean total number of ID50s (*i.e.*, dosage sufficient to infect 50 percent of exposed cattle) [correct?] from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of ID50s from adult cattle deadstock presented to the feed system was 37,000. This illustrates the risk of "4D cattle" (*i.e.*, deadstock).

Harvard Risk Assessment, 2001, Appendix 3A Base Case.

Subcommittee to the USDA's Foreign Animal and Poultry Disease  
Advisory Committee

An international panel of transmissible spongiform encephalopathy (TSE) experts appointed by Secretary of Agriculture Ann M. Veneman as a subcommittee to the Foreign Animal and Poultry Disease Advisory Committee issued a report in February 2004 which stated:

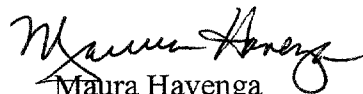
“... given the epidemiological evidence indicating that BSE agent  
was already circulating in ruminant feed prior to the feed ban in  
1997, and  
the integration of the North American cattle and feed industries,  
strong consideration should be given to excluding all SRM from  
**both the human food and animal feed supplies.**

“Considering the BSE situation in North America, the  
subcommittee believes the partial (ruminant to ruminant) feed  
ban that is currently in place is insufficient to prevent exposure  
of cattle to the BSE agent.”

Secretary's Advisory Committee on Foreign Animal and Poultry  
Diseases' Subcommittee on the United States' Response to the  
Detection of a Case of Bovine Spongiform Encephalopathy, Report on  
Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the  
United States, 2 February 2004, p. 8 (emphasis added).

In conclusion, we urge the FDA to adhere to the advice of both  
international and domestic experts and issue without undue delay  
additional regulations prohibiting the inclusion of SRMs and deadstock  
in feed for all animals. We further urge FDA to discontinue all of the  
exemptions to the existing feed ban (with the exception of the  
exemption for milk), which still allow the feeding of ruminant protein  
to ruminants.

Respectfully submitted,



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